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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/572,027	12/14/1995	LORIN R. DEBONTE	A21-535.1007	3481

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EXAMINER	
NELSON, AMY J	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/572,027	Lorin R. DeBonte, et al.
Examiner	**Art Unit**
Amy Nelson	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) X Responsive to communication(s) filed on *response filed 2/14/01 and petition decision of 8/23/02* .

2a) ☐ This action is **FINAL**. 2b) X This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-3, 5-10, 27-29, 31-35, 37-46, and 55-70* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) X Claim(s) *1-3, 5-10, 27-29, 31-35, 37-46, and 55-70* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) X The specification is objected to by the Examiner.

10) X The drawing(s) filed on *Dec 14, 1995* is/are a) X accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) X The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) X Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) X Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) X Information Disclosure Statement(s) (PTO-1449) Paper No(s). 41
4) ☐ Interview Summary (PTO-413) Paper No(s).
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-3, 5-10, 27-29, 31-35, 37-46, and 55-70 are pending.

2. Prosecution is hereby reopened in view of the following new grounds of rejection.

Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

The Specification contains sequences that do not have sequence identifiers. For example, see pages 15-17, and page 62.

In addition, clarification of the sequence identifiers is required. It is entirely unclear what form of the enzyme each sequence identifier corresponds to. For example, the specification indicates that SEQ ID NO:1 is the wild-type D-form (pg 60, line 25), the mutant D form (pg 25, line 26) and the mutant F form (the preliminary amendment filed September 16, 1997). The mutant D form is identified as being encoded by SEQ ID NO:1 (pg 25, line 26), SEQ ID NO:5 (the preliminary amendment filed September 16, 1997), and SEQQ ID NO:3 (pg 60, line 24). Nowhere does the specification indicate which sequence identifier corresponds to the sequence for the F-form. Clarification of this matter, without introduction of new matter, is required.

Full compliance with the Sequence Rules is required in response to this Official action. A complete response to this Official action should include both compliance with the Sequence Rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Official action will be held to be non-responsive.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The declarations signed by DeBonte and Miao state that the application was amended on 27 March, 1996; 12 September, 1997; 21 April, 1998; 25 September, 1998; 3 November, 1998; and 9 May, 2001, while the declaration signed by joint inventor Zhegong Fan states that the application was amended only on 27 March, 1996; 12 September, 1997; 21 April, 1998; 25 September, 1998, and 3 November, 1998. Additionally, the declarations signed by DeBonte and Miao reflect a different residence and mailing address for Fan than the declaration which Fan has signed. A new oath or declaration in compliance with 37 CFR 1.63 and 1.67, listing all of the amendments and signed by joint inventor Fan must be submitted.

Furthermore, it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability

as defined in 37 CFR 1.56. In particular, Applicant must acknowledge the duty to disclose all information known to be material to patentablity which became available betwen the filing date of parent applications: 08/416,497; 07/739,965; 07/575,542 and the filiing date of the instant application.

Specification

5. The amendment filed 9/16/97 is objected to under 35 U.S.C. 132 because it introduces NEW MATTER into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The amendments to the Specification and the Sequence Listing filed September 16, 1997. By the amendment, Applicant attempts to change the labeling of the sequences in the Sequence Listing to change the D and F form, and to change the plant source of the nucleic acid. Also, Applicant attempts to change the location of the mutation between a T to A transversion at position 515 and a G to A transversion at position 316. Although there is support for the two mutation location in the specification, there is not clear support for the sequences of the nucleic acids from the different plant lines, e.g. wild type, and the two mutants, Q508 and IMC 129. Hence, there is no support in the specification to support the introduced changes in the context of the specific sequences. The Declaration filed April 24, 1998 does not obviate the objection because Applicant merely explains the error in the as-filed specification. While it is unfortunate that Applicant's

original filing was incorrect, a new matter problem still arises when Applicant attempts to introduce material unsupported by the specfication as filed.

Furthermore, the amendments to the Specification filed April 1, 1996 are not supported by the Specification as filed. For example, the introduction of Table 6, replacement of "<50%" with --<5.0%--, and replacement of "Leaf lipid" with --Lipid-- all constitute new matter.

Applicant must point to support for the changes to the Specification and to the Sequence Listing, or Applicant must cancel the NEW MATTER in response to this Office Action.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should reflect the claimed invention which is directed to mutant *Brassica* plants with high oleic acid and low linoleic acids.

7. The abstract of the disclosure is objected to because it does not reflect the claimed invention, directed to mutant *Brassica* plants with high oleic acid and low linoleic acids. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-3, 5-10, 27-29, 31-35, 37-46, and 55-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated mutant nucleic acid fragment of at least 20 nucleotides from a Brassicaceae or *Helianthus* delta-12 fatty acid desaturase gene having a mutation in a His-Xaa-Xaa-Xaa-His motif, and Applicant claims an isolated mutant nucleic acid fragment of at least 20 nucleotides from a Brassicaceae delta-15 fatty acid desaturase gene having a mutation in a His-Xaa-Xaa-Xaa-His motif. Applicant further claims plants comprising said nucleic acids, and methods of selecting plants comprising said mutant nucleic acids.

Although the specification and Sequence Listing are in disagreement, Applicant appears to describe the sequences of a mutant and wild-type delta-12 fatty acid desaturase nucleic acid from *Brassica napus* (SEQ ID NO:1 as compared to SEQ ID NO:3), wherein the mutation is G to A transversion at nucleotide 316, resulting in amino acid substitution of glutamic acid for lysine. Applicant also discloses another mutation which is a T to A transversion at nucleotide 515, resulting in an amino acid substitution of leucine for histidine (SEQ ID NO:5 compared to SEQ ID NO:7). Applicant does not describe other mutant nucleic acid fragments from other species of Brassicaceae or from *Helianthus*, and Applicant does not describe fragments of as small as 20 nucleotides that encode mutant delta-12 or delta-fatty acid desaturase. Therefore, the plants, and methods of making mutant plants are similarly not described throughout the broad scope of the claims.

See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)., which teaches that "A description of a genus of cDNAs may be achieved by

means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus."

10. Claims 1-3, 5-10, 27-29, 31-35, 37-46, and 55-70 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims an isolated mutant nucleic acid fragment of at least 20 nucleotides from a Brassicaceae or *Helianthus* delta-12 fatty acid desaturase gene having a mutation in a His-Xaa-Xaa-Xaa-His motif, and Applicant claims an isolated mutant nucleic acid fragment of at least 20 nucleotides from a Brassicaceae delta-15 fatty acid desaturase gene having a mutation in a His-Xaa-Xaa-Xaa-His motif. Applicant further claims plants comprising said nucleic acids, and methods of selecting plants compirising said mutant nucleic acids.

Applicant teaches EMS mutagenesis of *Brassica napus* seeds, production of plants therefrom, GC analysis of fatty acid content of the plants, and development of plant lines with particular fatty acid profiles by repeated selfing of said plants (Exampes 1-9). Applicant teaches MNNG mutagenesis of *Brassica napus* seeds, screening of plants produced therefrom for high oleic and low linoleic acid content, and development of the lines IMC129 and Q508 (Example 10). Applicant teaches RT-PCR of the D and F form of the delta-12 desaturase from the two lines and comparison to the same genes from the wild type line, Westar. Although the specification and Sequence Listing

are contradictory, it appears that Applicant teaches that IMC129 and Q508 differ from Westar in the D form by a G to A transversion at nucleotide 316 resulting in a single amino acid change from lysine to glutamic acid, and that Q508 differs from Westar in the F form by a T to A transversion at nucleotide 515 resulting in a single amino acid change from histidine to leucine. Applicant does not teach a repeatable method of making the disclosed mutant plants that were isolated by mutagenesis, and Applicant does not teach a use for the isolated mutant nucleic acids.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

EMS and MNNG mutagenesis are highly unpredictable means of introducing mutations in plants. Mutations may occur in any plant at any location on the genome of the plant. For example, in *Brassica napus*, it is estimated that the genome size is 1129-1235 megabasepairs (see enclosed, http://www.brassica.info/genomesize.htm). Hence, mutations may occur at any of 1.2 billion bases. Applicant's isolation of the two plant lines (IMC129 and Q508) with particular fatty acid profiles appears to have been fortuitous, as Applicant did not have any kind of selection step in the screening. Mutagenized plants were simply assayed by gas chromatography for their fatty acid profiles, and plants with desirable fatty acid content were developed into plant lines. Hence, Applicant does not

provide a repeatable method for isolating the disclosed mutant plant lines, or plant lines with the same or similar mutations. Moreover, Applicant does not teach a use for the claimed nucleic acids. Although the claimed nucleic acids are present in the mutant plants, Applicant has not taught how to use the isolated nucleic acids. In Example 14, Applicant discusses development of primers that allow one to distinguish the mutant from the wild type lines. However, Applicant does not disclose the sequence of those primers, nor PCR reaction conditions that would allow selective binding to and amplification of one of the mutant or wild type genomic DNA and not the other. Moreover, Applicant does not propose a use for the primers other than to distinguish their already developed plant lines. In the absence, of appropriate guidance, it is submitted that Applicant has not enabled the invention.

When the *Wands* factors are weighed it is concluded that undue experimentation would be required to practice the invention. In view of the breadth of the claims, the unpredictability in the art of plant mutagenesis and selection at the time of filing of the application, the lack of appropriate guidance, and the presence of only two working examples that do not allow reproducible production of the claimed plants, it is submitted that Applicant has not enabled the invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 3, 5, 6, 9, 10, 29, 35, 37-45, and 55-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 3, "said mutant desaturase gene" lacks proper antecedent basis.

At Claim 5, line 2, "said at least one mutation in said gene" lacks proper antecedent basis, and should be changed to --said at least one mutation in a region of said desaturase gene--.

At Claim 6, line 2, the term "comprises" should be changed to --has-- for clarity.

At Claim 9, line 2, the term "D form" is unclear. Applicant does not define the term in the specification, and hence it is not known what is encompassed by the term. Appropriate correction is required.

At Claim 12, "said mutant desaturase gene" lacks proper antecedent basis.

At Claim 35, line 2, before "said" it is recommended that --wherein-- be inserted, and after "mutation" that --is-- be inserted, for clarity.

At Claim 55, line 5, the phrase "progeny plants" does not make sense in the instant context. Plants can be produced from cells, but progeny plants can only be produced from other plants.

At Claim 55, line 11, "said delta-12 gene mutation" lacks proper antecedent basis.

Claim 55, step (d) does not make sense. A plant "line" is produced only after repeated selfing. Hence, it is not clear how a plant line can be produced by cross pollination alone or by a single self-pollination. Appropriate correction is required.

At Claim 57, lines 6-7, "said plant line cells" lacks proper antecedent basis.

At Claim 57, lines 8-9, "said plant line progeny plants" lacks proper antecedent basis.

At Claim 57, lines 10-11, "said at least one delta-15 gene mutation" lacks proper antecedent basis.

At Claim 57, lines 15-16, "said at least one plant line progeny plant" lacks proper antecedent basis.

Claim 57, step (h) does not make sense. A plant "line" is produced only after repeated selfing. Hence, it is not clear how a plant line can be produced by cross pollination alone or by a single self-pollination. Appropriate correction is required.

At Claim 61, lines 5-6, "said plant line cells" lacks proper antecedent basis.

At Claim 61, lines 7-8, "said plant line progeny plants" lacks proper antecedent basis.

At Claim 61, lines 12-13, "said at least one plant line progeny plant" lacks proper antecedent basis.

Claim 61, step (h) does not make sense. A plant "line" is produced only after repeated selfing. Hence, it is not clear how a plant line can be produced by cross pollination alone or by a single self-pollination. Appropriate correction is required.

At Claim 64, line 5, the phrase "progeny plants" does not make sense in the instant context. Plants can be produced from cells, but progeny plants can only be produced from other plants.

Claim 64, step (d) does not make sense. A plant "line" is produced only after repeated selfing. Hence, it is not clear how a plant line can be produced by cross pollination alone or by a single self-pollination. Appropriate correction is required.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:30 AM - 5:00 PM.

The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to Customer Service 1600, whose telephone number is (703) 305-0198.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Amy J. Nelson, Ph.D.

March 14, 2003